REMARKS

Claims 1-14, 17-18, and 21 constitute the pending claims in the present application. Claims 4-9 and 11-13 are withdrawn from consideration. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Rejection based on 35 U.S.C. 103(a). Claims 1-3, 10, 14, and 16-17 are rejected as being unapatentable over Smith (5,378,475) in view of Wong (6,331,313) and further in view of Heller (3,811,444). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action states that Smith teaches a sustained release drug delivery device including an inner core with the agent (including carbonic anhydrase inhibitors) and coating layers, wherein a first coating layer is essentially impermeable to the passage of agent and a second coating layer is permeable to the passage of agent; however, Smith does not teach the particular carbonic anhydrase inhibitors acetazolamide, methazolamide, ethoxzolamide, dichlorophenamide, dorzolamide, and brinzolamide.

The Office Action states that Wong teaches a controlled release biocompatible ocular drug delivery device that comprises a substantially impermeable polymeric outer layer covering a drug core, wherein the drug core may comprise carbonic anhydrase inhibitors such as acetazolamide, methazolamide, dichlorophenamide, etc. The Office Action further states that Wong teaches that the drug may be dispersed in a polymer matrix; however, neither Smith nor Wong teach an outer or second layer comprising a carbonic anhydrase inhibitor.

The Office Action states that Heller teaches a device comprising three concentric layers, wherein the outer layer comprises particles of drug. The Office Action further states that it would have been obvious to one of skill in the art at the time the invention was made to make the sustained release device of Smith, combine it with the carbonic anhydrase inhibitors and bioerodible polymer

matrix core of Wong, and further combine it with the outer layer that comprises drug as suggested by Heller.

With regard to Smith, Applicants respectfully draw the Examiner's attention to the results section of Example 3 which states that "[t]his is a ***non-biodegradable*** system. Although this may be considered a drawback, the reliable release rates over extended periods of time and the lack of inflammatory response would be very difficult to obtain using an erodible drug delivery system."

Similarly, Wong discloses devices that wherein the outer layer degrades ***after the drug has been released for the desired duration*** (see column 9, lines 43-45). Applicants assert that both Smith and Wong teach away from the use of devices wherein the drug is released from the device as a result of the degradation of the device.

In contrast, Heller discloses ***only*** bioerodible drug formulations comprising hydrophobic poly(carboxylic acid) having, an average of one ionizable carboxylic hydrogen for each eight to twenty two total carbon atoms. Such devices release drug over time as the polymer erodes. Applicants assert that both Smith and Wong ***teach away*** from the use of devices where the drug is released through bioerosion of the device, and make clear that the desired release rates depend on this characteristic. Applicants therefore assert that a person of skill in the art would not have been motivated to combine the teachings of Wong and Smith with the teachings of Heller, and indeed would have been motivated to avoid such a biodegradable system and its associated release characteristics. Similarly, Applicants assert that there would have been no reasonable expectation of success. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection based on 35 U.S.C. 103(a). Claims 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (5,902,598) in view of Wong (6,331,313) and further in view of Heller (3,811,444). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action states that Chen teaches sustained release drug delivery devices including a drug containing inner core, and a first coating layer, a second coating layer, and a third coating layer. The Office Action further states that Chen does not expressly teach carbonic anhydrase inhibitors as active agents. The Office Action additionally states that it would have been obvious to one of ordinary skill in the art to made the sustained release drug delivery device as suggested by Chen, combine it with the ocular drug delivery device including carbonic anhydrase inhibitors of Wong, and further combine it with the outer layer of an ocular insert that includes a drug as suggested by Heller.

Applicants assert that Chen discloses only ***non-biodegradable*** sustained release drug delivery systems. More particularly, Applicants respectfully draw the Examiner's attention to column 2, lines 17-24 which states that "[d]evices formed of polymeric materials that are insoluble in tear fluid retain their shape and integrity during the course of the needed therapy to serve as a drug reservoir for continuously administering a drug to the eye and the surrounding tissues at a rate that is not effected by dissolution or erosion of the polymeric material. Upon termination of the desired therapeutic program, the device is removed from the cul-de-sac." Further, Applicants respectfully draw the Examiner's attention to column 10, lines 62-64 which states that the disclosed devices "may remain in the vitreous permanently after treatment is complete."

Similarly, Wong discloses devices that wherein the outer layer degrades ***after the drug has been released for the desired duration*** (see column 9, lines 43-45). Applicants assert that both Chen and Wong teach away from the use of devices wherein the drug is released from the device as a result of the degradation of the device.

In contrast, Heller discloses ***only*** bioerodible drug formulations comprising hydrophobic poly(carboxylic acid) having, an average of one ionizable carboxylic hydrogen for each eight to twenty two total carbon atoms. Such devices release drug over time as the polymer erodes. Applicants assert that both Chen and Wong ***teach away*** from the use of devices where the drug is released through bioerosion of the device. Applicants therefore assert that a person of skill in the art would not have been motivated to combine the teachings of Chen and Wong with the teachings of

Heller. Similarly, Applicants assert that there would have been no reasonable expectation of success. Applicants respectfully request reconsideration and withdrawal of this rejection.

Double patenting. Claims 1-3, 14, 16-18, and 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 14, 16-18 and 20-21 of copending application 10/762,439.

Pursuant to MPEP 804(I)(B), "[t]he 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining in at least one of the applications."

Applicants agree to submit a terminal disclaimer at the appropriate time, if necessary.

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Applicants believe no additional fee is due with this response, aside from the Petition for Extension of Time. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. CDSI-P01-040 from which the undersigned is authorized to draw.

Dated: June 19, 2009

Respectfully submitted,

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